

**Translation**

PATENT COOPERATION TREATY

PCT/JP2003/014339



**PCT**

**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 3121WO0P	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/JP2003/014339	International filing date (day/month/year) 12 November 2003 (12.11.2003)	Priority date (day/month/year) 13 November 2002 (13.11.2002)
International Patent Classification (IPC) or national classification and IPC C12N 15/09, C12Q 1/02, 1/68, G01N 33/15, 33/50, 33/53, C07K 14/47, A61K 31/7088, 39/395, 45/00, 48/00, A61P 3/10, 13/12		
Applicant TAKEDA CHEMICAL INDUSTRIES, LTD.		

<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of _____ sheets.</p>
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>

Date of submission of the demand 11 December 2003 (11.12.2003)	Date of completion of this report 11 June 2004 (11.06.2004)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP2003/014339

## I. Basis of the report

### 1. With regard to the elements of the international application:\*

- ☒ the international application as originally filed
- ☐ the description:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the claims:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, as amended (together with any statement under Article 19  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the drawings:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the sequence listing part of the description:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

### 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

### 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

### 4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/fig \_\_\_\_\_

### 5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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## III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 32-37

because:

☒ the said international application, or the said claims Nos. 34, 35  
relate to the following subject matter which does not require an international preliminary examination (*specify*):

The subject matters of claims 34 and 35 relate to a method for treatment of mammals including the human by prevention or therapy, which does not require an international preliminary examination by the International Preliminary Examining Authority.

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 32, 33, 36, 37  
are so unclear that no meaningful opinion could be formed (*specify*):

The "TSC-22 inhibitors" of claims 32, 33, 36 and 37 are compounds obtained by screening. However, since the specification does not state any particular compounds at all as the TSC-22 inhibitors obtained by screening, the TSC-22 inhibitors are neither supported nor disclosed by the specification. Furthermore, even considering the common general technical knowledge prevailing on the filing date of the present application, what compounds are particularly included and what compounds are not included are unknown at all, and the description of the said claims is very unclear. Therefore, no significant statement can be presented with regard to the subject matters of the said claims.

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported  
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 32-37

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

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**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims	1-31	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-31	NO
Industrial applicability (IA)	Claims	1-31	YES
	Claims		NO

**2. Citations and explanations**

Document 1: US, 5958690, A (Incyte Pharm Inc.), 28 September, 1999 (28.09.99)

Document 2: "TGF- $\beta$ -stimulated Clone-22 (TSC-22) Represses the Transcription of Insulin Gene," (Y. Ihara, et al.), Diabetes, 2001, Vol. 50, Sup. 2, pages A342-A343

**Claims 1-31**

Document 1 describes the amino acid sequence of human TSC-22 homologue.

Document 2 describes that (1) when the gene expression of a pancreatic  $\beta$  cell of a type II diabetes model mouse was examined to identify a gene relating to type II diabetes, the expression of TSC-22 was found to rise, and (2) since TSC-22 inhibited the transcription of insulin, TSC-22 is considered to be a gene relating to type II diabetes.

In this situation, since the amino acid sequence described in Figure 1A of document 1 agrees with the amino acid sequence represented by SEQ ID NO: 2 of the present application, a person skilled in the art could have easily conceived of (1) using the protein having the amino acid sequence of document 1 or the gene encoding the protein and (2) screening the preventives and remedies for renal diseases such as diabetes based on the description of document 2.

Furthermore, a person skilled in the art could also have easily conceived of using the antibody bound to human TSC-22 as a preventive, remedy or diagnostic drug of diseases from the descriptions of documents 1 and 2.

Therefore, a person skilled in the art could have easily arrived at the subject matters of claims 1-31 based on the descriptions of documents 1 and 2.